10/698,031 :

Filed October 29, 2003

AMENDMENTS TO THE CLAIMS

Please amend the claims as indicated below. Additions are underlined and deletions are stricken through.

1. (Currently amended) An apparatus for treating cardiovascular disease in a medical patient, the apparatus comprising:

a sensor module, comprising a sensor, said sensor operable to generate a sensor signal indicative of a fluid pressure within a left atrium of a heart, and electronics;

an implantable cardiac rhythm management apparatus, said cardiac rhythm management apparatus comprising a housing and an electrode, said electrode operable to deliver an electrical stimulus to a location in the heart, said electrical stimulus delivered based at least in part on said sensor signal, wherein the sensor is connected to the implantable housing;

at least one implantable lead coupled to said implantable housing, and coupled to said electrode;

- a signal processor, operable to generate a processor output indicative of a treatment, wherein said processor output is based at least in part on the sensor signal; and
- a signaling device, operable to generate at least two treatment signals distinguishable from one another by the patient, each signal indicative of a therapeutic treatment, wherein said at least two treatment signals are based at least in part on said processor output.
- 2. (Original) The apparatus of Claim 1, wherein the cardiac rhythm management apparatus comprises a pacemaker.
- The apparatus of Claim 1, wherein the cardiac rhythm management 3. (Original) apparatus comprises a defibrillator.
- The apparatus of Claim 1, further comprising an external patient 4. (Original) advisory module.
- (Previously presented) The apparatus of Claim 4, wherein the external patient advisory module comprises an external telemetry device, the signal processor, and the signaling device.

10/698,031

Filed

: October 29, 2003

6. (Original) The apparatus of Claim 4, wherein the external patient advisory module further comprises a barometer configured to sense atmospheric pressure.

- 7. (Original) The apparatus of Claim 1, wherein the sensor comprises a pressure transducer.
- 8. (Original) The apparatus of Claim 1, wherein the sensor is in pressure communication with the left atrium.
- 9. (Original) The apparatus of Claim 1, wherein the sensor is located in the atrial septum.
- 10. (Original) The apparatus of Claim 1, wherein the sensor is located in the left atrium.
- 11. (Original) The apparatus of Claim 1, wherein the sensor is located in a location selected from the group consisting of one or more of the following: a right atrial appendage, a left atrial appendage, a pulmonary artery, a pulmonary vein, a pulmonary capillary wedge position, a right ventricle, a left ventricle, a right atrium, an intrathoracic space, and a central vein.
- 12. (Original) The apparatus of Claim 1, wherein the sensor comprises a low compliance titanium foil.
- 13. (Original) The apparatus of Claim 1, wherein the sensor comprises at least one silicon strain gauge.
- 14. (Original) The apparatus of Claim 1, wherein the sensor signal is a pressure signal.
 - 15. (Canceled)
- 16. (Original) The apparatus of Claim 14, wherein the pressure signal comprises a left atrial pressure.
- 17. (Original) The apparatus of Claim 14, wherein the pressure signal comprises a parameter of a left atrial pressure.
- 18. (Original) The apparatus of Claim 17, wherein the parameter comprises a parameter selected from the group consisting of one or more of the following: mean left atrial pressure, temporally filtered left atrial pressure, heart rate, respiratory variation of left atrial pressure, and respiration rate.

Appl. No. : 10/698,031

Filed : October 29, 2003

19. (Original) The apparatus of Claim 17, wherein the parameter is determined based upon at least one wave selected from the group consisting of one or more of the following: an a wave, a v wave, and a c wave.

- 20. (Original) The apparatus of Claim 17, wherein the parameter is determined based upon a parameter signal selected from the group consisting of one or more of the following: a wave amplitude, a waveform rate of ascent, a waveform rate of descent, timing of a wave feature with respect to a cardiac cycle, timing of a wave feature with respect to another wave feature, time difference between an a wave and a c wave, time difference between an a wave and a c wave.
- 21. (Original) The apparatus of Claim 17, wherein the parameter is determined based upon at least one descent selected from the group consisting of one or more of the following: an x descent, an x' descent, and a y descent.
- 22. (Original) The apparatus of Claim 17, wherein the parameter is determined based upon a parameter signal selected from the group consisting of one or more of the following: a descent amplitude, a descent rate of ascent, a descent rate of descent, timing of a descent feature with respect to a cardiac cycle, timing of a descent feature with respect to another wave feature, time difference between an x descent and an x' descent, time difference between an x descent and a y descent, and time difference between an x' descent and a y descent.
- 23. (Original) The apparatus of Claim 17, wherein the parameter of left atrial pressure is independent of ambient atmospheric pressure.
- 24. (Original) The apparatus of Claim 1, wherein the sensor signal is measured during an interval.
- 25. (Original) The apparatus of Claim 1, wherein the sensor signal is sampled in response to an event selected from the group consisting of one or more of the following: a detected event, a symptom, and an instruction.
 - 26. (Canceled)
- 27. (Currently amended) The apparatus of Claim <u>1</u>26, wherein the sensor module has a cylindrical shape.
- 28. (Original) The apparatus of Claim 27, wherein the sensor module has a length of about 8 mm, and a diameter of about 3 mm.

: 10/698,031

Filed

: October 29, 2003

- 29. (Original) The apparatus of Claim 27, wherein the sensor module has a length in a range between about 5 mm and about 15 mm, and a diameter in a range between about 1 mm and about 5 mm.
- 30. (Currently amended) The apparatus of Claim <u>1</u>26, wherein the sensor module is connected to the at least one implantable lead.
- 31. (Currently amended) The apparatus of Claim <u>1</u>26, wherein the sensor module is coupled to the implantable housing with an additional lead.
 - 32. (Canceled)
 - 33. (Canceled)
- 34. (Currently amended) The apparatus of Claim <u>1</u>33, wherein the electronics comprise an application-specific integrated circuit (ASIC).
- 35. (Currently amended) The apparatus of Claim <u>1</u>33, wherein the electronics comprise an analog-to-digital converter.
- 36. (Currently amended) The apparatus of Claim <u>1</u>33, wherein the electronics comprise circuitry for communicating a digital signal.
- 37. (Original) The apparatus of Claim 1, further comprising one or more additional sensors.
 - 38. (Original) The apparatus of Claim 1, wherein the housing is a flat oval shape.
- 39. (Original) The apparatus of Claim 38, wherein the housing comprises a first dimension and a second dimension, and the first dimension is about 30 mm, and the second dimension is about 20 mm.
- 40. (Original) The apparatus of Claim 1, wherein the housing is implanted near a shoulder in the medical patient.
- 41. (Original) The apparatus of Claim 1, wherein the housing is implanted at a site in the abdomen in the medical patient.
- 42. (Original) The apparatus of Claim 1, wherein the housing further comprises an antenna or coil.
- 43. (Original) The apparatus of Claim 1, wherein the housing further comprises a power source.

: 10/698,031

Filed

October 29, 2003

- 44. (Original) The apparatus of Claim 1, wherein the signaling device is at least partially located in the housing.
- 45. (Original) The apparatus of Claim 1, further comprising a telemetry apparatus.
- 46. (Original) The apparatus of Claim 45, wherein the telemetry apparatus is at least partially located within the housing.
- 47. (Original) The apparatus of Claim 45, wherein the signal processor is located in an external apparatus outside of the patient's body.
- 48. (Original) The apparatus of Claim 45, wherein the signaling device is located in an external apparatus outside of the patient's body.
- 49. (Original) The apparatus of Claim 47, wherein the external apparatus includes an external telemetry apparatus.
- 50. (Original) The apparatus of Claim 49, wherein the external telemetry apparatus is selected from the group consisting of one or more of the following: a personal digital assistant, a computer, a radio frequency telemetry hardware module, and a coil antenna.
- 51. (Original) The apparatus of Claim 45, wherein the telemetry apparatus is operable to communicate by reflected impedance of radio frequency energy.
- 52. (Original) The apparatus of Claim 45, wherein the telemetry apparatus is operable to communicate by frequency or amplitude shifting of radio frequency energy.
- 53. (Original) The apparatus of Claim 1, wherein the housing further comprises a data memory.
- 54. (Original) The apparatus of Claim 1, further comprising an external power source.
- 55. (Original) The apparatus of Claim 54, wherein the power source provides power through radio frequency coupling.
- 56. (Original) The apparatus of Claim 55, wherein the radio frequency is selected from the group consisting of one or more of the following: about 125 kHz, about 8192 Hz, about 10.9 kHz, and about 30 kHz.
- 57. (Original) The apparatus of Claim 1, wherein the operation of the cardiac rhythm management apparatus is controlled at least in part by the pressure signal.

: 10/698,031

Filed

October 29, 2003

58. (Original) The apparatus of Claim 1, wherein the signal processor comprises a personal digital assistant.

- 59. (Original) The apparatus of Claim 1, wherein at least a part of the signal processor is implanted within the medical patient.
- 60. (Original) The apparatus of Claim 1, wherein the signal processor is external to the medical patient.
- 61. (Original) The apparatus of Claim 1, wherein the at least one implantable lead comprises a pacemaker lead.
- 62. (Original) The apparatus of Claim 1, wherein the at least one implantable lead comprises a defibrillator lead.
- 63. (Original) The apparatus of Claim 1, wherein the at least one implantable lead carries a lead signal.
- 64. (Original) The apparatus of Claim 63, wherein the lead signal is selected from the group consisting of one or more of the following: an electrical signal, a hydraulic signal, an optical signal, and an ultrasonic signal.
- 65. (Original) The apparatus of Claim 1, wherein the at least one implantable lead communicates the sensor signal to said implantable housing.
- 66. (Original) The apparatus of Claim 65, wherein said sensor signal and said electrical stimulus are provided by the at least one implantable lead.
- 67. (Original) The apparatus of Claim 1, wherein the at least one implantable lead provides one or more power pulses between said implantable housing and said sensor.
- 68. (Original) The apparatus of Claim 1, wherein the at least one implantable lead provides a data signal between said implantable housing and said sensor.
- 69. (Original) The apparatus of Claim 68, wherein the data signal consists of a signal selected from the group consisting of one or more of the following: a pressure signal, a non-pressure sensing signal, a pacing signal and a programming signal.
- 70. (Original) The apparatus of Claim 1, wherein the signaling device comprises a personal digital assistant.
- 71. (Original) The apparatus of Claim 70, wherein the processor output comprises a text or graphics display.

: 10/698,031

Filed

: October 29, 2003

- 72. (Original) The apparatus of Claim 1, wherein the signaling device comprises a device selected from the group consisting of one or more of the following: an electrical buzzer, an alarm, and a telephone.
 - 73. (Original) The apparatus of Claim 1, further comprising at least one anchor.
- 74. (Original) The apparatus of Claim 1, further comprising an automated therapy device.
- 75. (Original) The apparatus of Claim 74, wherein the automated therapy device is selected from a therapy device selected from one or more of the following: a dynamic prescription, drug delivery unit, and a cardiac rhythm management apparatus
- 76. (Original) The apparatus of Claim 74, wherein the automated therapy device controls the AV interval of a dual chamber pacemaker.
- 77. (Original) The apparatus of Claim 74, wherein the automated therapy device is at least partially controlled based upon parameters indicative of congestive heart failure.
- 78. (Original) The apparatus of Claim 74, wherein the automated therapy device is at least partially controlled based upon parameters indicative of atrial fibrillation.
- 79. (Original) The apparatus of Claim 1, wherein said signal processor generates said processor output based in part on a physician's dynamic prescription, said dynamic prescription comprising at least two treatment instructions corresponding to at least two distinct physiological conditions.
- 80. (Original) The apparatus of Claim 79, further comprising a physician workstation configured to receive and store a dynamic prescription.
- 81. (Original) The apparatus of Claim 80, further comprising an interface for communicating said stored dynamic prescription from said physician workstation to said signal processor.
- 82. (Original) The apparatus of Claim 1, wherein at least one treatment signal comprises a patient instruction.
- 83. (Original) The apparatus of Claim 1, wherein at least one treatment signal is a numerical designation.
- 84. (Original) The apparatus of Claim 83, wherein said numerical designation is indicative of a pressure measurement.

: 10/698,031

Filed

October 29, 2003

- 85. (Original) The apparatus of Claim 1, wherein said at least two treatment signals are numerical designations.
- 86. (Original) The apparatus of Claim 1, wherein at least one treatment signal is based at least in part on two or more physician instructions.
- 87. (Original) The apparatus of Claim 1, wherein at least one treatment signal is provided to a user.
- 88. (Original) The apparatus of Claim 1, wherein said cardiovascular disease is congestive heart failure.
- 89. (Previously presented)The apparatus of Claim 1, wherein said implantable lead is upgradable.
- 90. (Previously presented)The apparatus of Claim 1, wherein said implantable lead is configured to operate in a plurality of configurations.
- 91. (Currently amended) An apparatus for treating cardiovascular disease in a medical patient, the apparatus comprising:
 - <u>a sensor module comprising electronics</u>, a first sensor and a second sensor, wherein said first sensor is operable to generate a first sensor signal indicative of a fluid pressure within the heart;
 - a cardiac rhythm management apparatus operable to deliver an electrical stimulus to a location in the heart, said electrical stimulus delivered based at least in part on said sensor signal;
 - at least one implantable lead coupled to said cardiac rhythm management apparatus, wherein the at least one implantable lead is configured to operate in a plurality of configurations;
 - a signal processor, operable to generate a processor output indicative of a treatment, wherein said processor output is based at least in part on the first sensor signal; and
 - a signaling device, operable to generate at least two treatment signals distinguishable from one another by the patient, each signal indicative of a therapeutic treatment, wherein said at least two treatment signals are based at least in part on said processor output.

: 10/698,031

Filed

: October 29, 2003

- 92. (Original) The apparatus of Claim 91, wherein said cardiac rhythm management apparatus comprises at least one electrode.
 - 93. (Canceled)
- 94. (Original) The apparatus of Claim 91, wherein the second sensor is located externally to the patient.
- 95. (Original) The apparatus of Claim 91, wherein the second sensor measures a physical dimension.
- 96. (Original) The apparatus of Claim 95, wherein the physical dimension is selected from the group consisting of one or more of the following: a left atrial dimension, a left atrial cross-sectional area, a left atrial volume, a left ventricular dimension, a left ventricular cross-sectional area, and a left ventricular volume.
- 97. (Original) The apparatus of Claim 91, wherein the second sensor measures a parameter selected from the group consisting of one or more of the following: a second pressure, electrical activity of the heart, a temperature, an atrial septum position, a velocity of a cardiac structure, an acceleration of a cardiac structure, an electrical resistance, a thoracic electrical impedance, a respiratory tidal volume, a respiratory rate, a respiratory minute volume, a total body weight, oxygen saturation, oxygen partial pressure, oxygen partial pressure in a left chamber of a heart, oxygen partial pressure in a right chamber of a heart, and cardiac output.
- 98. (Original) The apparatus of Claim 91, wherein the second sensor comprises an automated arterial pressure cuff.
- 99. (Original) The apparatus of Claim 91, wherein the second sensor comprises a weight scale.
- 100. (Previously presented)The apparatus of Claim 91, wherein said implantable lead is upgradable.
 - 101.-118. (Canceled)
- 119. (Currently amended) An apparatus for treating cardiovascular disease in a medical patient, the apparatus comprising:
 - a sensor, operable to generate a pressure signal indicative of a fluid pressure within a left atrium of a heart;

: 10/698,031

Filed

: October 29, 2003

a cardiac rhythm management apparatus, said cardiac rhythm management apparatus comprising an electrode, said electrode operable to deliver an electrical stimulus to a location in the heart, said electrical stimulus delivered based at least in part on said pressure signal;

a telemetry apparatus, operable to transmit said pressure signal to a location outside of said medical patient, wherein the cardiac rhythm management apparatus and the telemetry apparatus are at least partially contained within an implantable housing;

at least one implantable lead coupled to said electrode;

a signal processor, operable to generate a processor output indicative of a therapeutic treatment, said processor output based at least in part on the pressure signal; and

a signaling device, operable to communicate the processor output to the medical patient; and

an external patient advisory module located external to said medical patient.

- 120. (Canceled)
- 121. (Canceled)
- 122. (Currently amended) The apparatus of Claim <u>119121</u>, wherein the external patient advisory module comprises the external telemetry device, the signal processing apparatus, and the patient signaling device.
- 123. (Currently amended) The apparatus of Claim <u>119121</u>, wherein the patient advisory module further comprises a barometer for sensing atmospheric pressure.
- 124. (Previously presented) The apparatus of Claim 119, wherein said implantable lead is upgradable.
- 125. (Previously presented) The apparatus of Claim 119, wherein said implantable lead is configured to operate in a plurality of configurations.
 - 126.-145. (Canceled)
- 146. (Currently amended) An apparatus for treating cardiovascular disease in a medical patient, the apparatus comprising:

10/698,031

Filed

: October 29, 2003

a sensor, operable to generate a sensor signal indicative of a fluid pressure within a left atrium of a heart, wherein the sensor is configured to be implanted in the atrial septum of the heart;

a cardiac rhythm management apparatus, operable to deliver an electrical stimulus to a location in the heart;

- a signal processor, operable to generate a processor output indicative of a treatment, wherein said treatment signal is based at least in part on the sensor signal; and
- a signaling device, operable to generate at least two treatment signals distinguishable from one another by the patient, each signal indicative of a therapeutic treatment, wherein said at least two treatment signals are based at least in part on said processor output, and wherein the signaling device is located in an external apparatus outside of the patient's body.
- 147. (Previously presented) The apparatus of Claim 146, wherein the sensor is located in a location selected from the group consisting of one or more of the following: a right atrial appendage, a left atrial appendage, a pulmonary artery, a pulmonary vein, a pulmonary capillary wedge position, a right ventricle, a left ventricle, a right atrium, an intrathoracic space, and a central vein.
- 148. (Previously presented)The apparatus of Claim 146, wherein the sensor signal is a pressure signal.
- 149. (Previously presented)The apparatus of Claim 146, wherein the sensor is connected to an implantable housing.
- 150. (Previously presented)The apparatus of Claim 149, wherein the implantable housing is implanted near a shoulder in the medical patient.
- 151. (Previously presented)The apparatus of Claim 146, further comprising a telemetry apparatus.
 - 152. (Canceled)
- 153. (Previously presented)The apparatus of Claim 146, wherein the signal processor comprises a personal digital assistant.

10/698,031

Filed

: October 29, 2003

154. (Previously presented)The apparatus of Claim 146, wherein the signaling device comprises a personal digital assistant.

155. (Currently amended) An apparatus for treating cardiovascular disease in a medical patient, the apparatus comprising:

a sensor, <u>located in the atrial septum and</u> operable to generate a sensor signal indicative of a fluid pressure within a left atrium of a heart;

an implantable cardiac rhythm management apparatus, said cardiac rhythm management apparatus comprising a housing and an electrode, said electrode operable to deliver an electrical stimulus to a location in the heart, said electrical stimulus delivered based at least in part on said sensor signal, wherein the housing is configured to be implanted near a shoulder in the medical patient;

at least one implantable lead coupled to said implantable housing, and coupled to said electrode;

a signal processor, operable to generate a processor output indicative of a treatment, wherein said processor output is based at least in part on the sensor signal; and

a signaling device, operable to generate at least two treatment signals distinguishable from one another by the patient, each signal indicative of a therapeutic treatment, wherein said at least two treatment signals are based at least in part on said processor output.

- 156. (Canceled)
- 157. (Canceled)
- 158. (Previously presented)The apparatus of Claim 155, wherein the sensor signal is a pressure signal.
- 159. (Previously presented)The apparatus of Claim 155, wherein the sensor is connected to the implantable housing.
- 160. (Previously presented) The apparatus of Claim 155, further comprising a telemetry apparatus.

: 10/698,031

Filed

: October 29, 2003

161. (Previously presented) The apparatus of Claim 155, wherein the signaling device is located in an external apparatus outside of the patient's body.

- 162. (Previously presented)The apparatus of Claim 155, wherein the signal processor comprises a personal digital assistant.
- 163. (Previously presented)The apparatus of Claim 155, wherein the at least one implantable lead provides one or more power pulses between said implantable housing and said sensor.
- 164. (Previously presented)The apparatus of Claim 155, wherein the signaling device comprises a personal digital assistant.
- 165. (Previously presented)An apparatus for treating cardiovascular disease in a medical patient, the apparatus comprising:

a sensor, operable to generate a sensor signal indicative of a fluid pressure within a left atrium of a heart;

an implantable cardiac rhythm management apparatus, said cardiac rhythm management apparatus comprising a housing and an electrode, said electrode operable to deliver an electrical stimulus to a location in the heart, said electrical stimulus delivered based at least in part on said sensor signal;

at least one implantable lead coupled to said implantable housing, and coupled to said electrode;

- a signal processor, operable to generate a processor output indicative of a treatment, wherein said processor output is based at least in part on the sensor signal; and
- a signaling device, operable to generate at least two treatment signals distinguishable from one another by the patient, each signal indicative of a therapeutic treatment, wherein said at least two treatment signals are based at least in part on said processor output, wherein the signaling device comprises a personal digital assistant.
- 166. (Previously presented) The apparatus of Claim 165, wherein the sensor is located in the atrial septum.
- 167. (Previously presented)The apparatus of Claim 165, wherein the sensor is located in a location selected from the group consisting of one or more of the following: a right atrial

: 10/698,031

Filed

: October 29, 2003

appendage, a left atrial appendage, a pulmonary artery, a pulmonary vein, a pulmonary capillary wedge position, a right ventricle, a left ventricle, a right atrium, an intrathoracic space, and a central vein.

- 168. (Previously presented)The apparatus of Claim 165, wherein the sensor signal is a pressure signal.
- 169. (Previously presented)The apparatus of Claim 165, wherein the sensor is connected to the implantable housing.
- 170. (Previously presented) The apparatus of Claim 165, wherein the housing is implanted near a shoulder in the medical patient.
- 171. (Previously presented)The apparatus of Claim 165, further comprising a telemetry apparatus.
 - 172. (Canceled)
- 173. (Previously presented)The apparatus of Claim 165, wherein the signal processor comprises a personal digital assistant.
- 174. (Previously presented)The apparatus of Claim 165, wherein the at least one implantable lead provides one or more power pulses between said implantable housing and said sensor.
- 175. (Previously presented)An apparatus for treating cardiovascular disease in a medical patient, the apparatus comprising:
 - a sensor, operable to generate a sensor signal indicative of a fluid pressure within a left atrium of a heart;
 - an implantable cardiac rhythm management apparatus, said cardiac rhythm management apparatus comprising a housing and an electrode, said electrode operable to deliver an electrical stimulus to a location in the heart, said electrical stimulus delivered based at least in part on said sensor signal;
 - at least one implantable lead coupled to said implantable housing, and coupled to said electrode;

: 10/698,031

Filed

•

October 29, 2003

a signal processor, operable to generate a processor output indicative of a treatment, wherein said processor output is based at least in part on the sensor signal; and

a signaling device, operable to generate at least two treatment signals distinguishable from one another by the patient, each signal indicative of a therapeutic treatment, wherein said at least two treatment signals are based at least in part on said processor output; and

at least one anchor coupled to the sensor.

- 176. (Previously presented)The apparatus of Claim 175, wherein the sensor is located in the atrial septum.
- 177. (Previously presented) The apparatus of Claim 175, wherein the sensor is located in a location selected from the group consisting of one or more of the following: a right atrial appendage, a left atrial appendage, a pulmonary artery, a pulmonary vein, a pulmonary capillary wedge position, a right ventricle, a left ventricle, a right atrium, an intrathoracic space, and a central vein.
- 178. (Previously presented)The apparatus of Claim 175, wherein the sensor signal is a pressure signal.
- 179. (Previously presented)The apparatus of Claim 175, wherein the sensor is connected to the implantable housing.
- 180. (Previously presented)The apparatus of Claim 175, wherein the housing is implanted near a shoulder in the medical patient.
- 181. (Previously presented)The apparatus of Claim 175, further comprising a telemetry apparatus.
- 182. (Previously presented) The apparatus of Claim 175, wherein the signaling device is located in an external apparatus outside of the patient's body.
- 183. (Previously presented)The apparatus of Claim 175, wherein the signal processor comprises a personal digital assistant.

: 10/698,031

Filed

: October 29, 2003

184. (Previously presented)The apparatus of Claim 175, wherein the at least one implantable lead provides one or more power pulses between said implantable housing and said sensor.

185. (Previously presented)The apparatus of Claim 175, wherein the signaling device comprises a personal digital assistant.